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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rabbani et al

Serial No. 08/978,635

Group Art Unit: 1635

Filed: November 25, 1997

Examiner: M. Schmidt

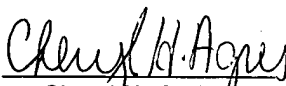
Title: PROCESS FOR SELECTIVE EXPRESSION OF NUCLEIC ACID PRODUCTS

TRANSMITTAL
INFORMATION DISCLOSURE STATEMENT

Mail Stop DD
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.: <u>EV160376573US</u>	
Deposit Date: <u>October 27, 2003</u>	
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Cheryl H. Agris Reg. Exhibit 34,086	<u>10/27/03</u> Date

10/29/2003 EFLDRES \ 00000146 051135 08978635

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Enz-53(D4)

10. [] A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

[X] Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **ENZ-53(D4)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: October 27, 2003

By: *Cheryl H. Agris*
Cheryl H. Agris
Registration No. 34,086

Mailing Address:

ENZO LIFE SCIENCES, INC.
c/o Enzo Biochem, Inc.
292 Madison Avenue, 9th Floor
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Telephone: (212) 583-0100
Telefax: (212) 583-0150

Enz-53(D4)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
 - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
 - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.

☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-53(D4). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
 - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Enz-53(D4)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Rabbani et al

Serial No. 08/978,635

Filed: November 25, 1997

Title: PROCESS FOR SELECTIVE EXPRESSION OF
NUCLEIC ACID PRODUCTS

Group Art Unit: 1635

Examiner: M. Schmidt

527 Madison Avenue, 9th Floor
New York, New York 10022
October 27, 2003

FILED VIA EXPRESS MAIL

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SECOND INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.56 & 1.971.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following sixteen (16) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

10/29/2003 EFLORES 00000146 08978635

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Enz-53(D4)

Rabbani et al

Serial No.: 08/978,635

Filed: November 25, 1997

Page 2 [Second Information Disclosure Statement

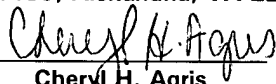
-- October 27, 2003]

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No.: EV160376573US

Deposit Date: October 27, 2003

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Cheryl H. Agris

Reg. Exhibit 34,086

10/27/03
Date

1. Chang, H-K, et al, "Block of HIV-1 infection by a combination of antisense tat RNA and TAR decoys: a strategy for control of HIV-1," Gene Therapy, Vol 1(3):208-216 (1994) [EXHIBIT 1]
2. Cohli, H., et al, "Inhibition of HIV-1 multiplication in a human CD4 lymphocytic cell line expressing antisense and sense RNA molecules containing HIV-1 packaging signal and rev response element(s)," Antisense Research and Development, Vol. 4:19-26 (1994) [EXHIBIT 2]
3. Tani, T., et al, "Activity of chimeric RNAs of U6 snRNA and (-)sTRSV in the cleavage of a substrate RNA," Nucleic Acids Research, Vol. 20(12):2991-2996 (1992) [EXHIBIT 3]
4. Michael, W.M., et al, "Signal sequences that target nuclear import and nuclear export of pre-mRNA-binding proteins," Cold Spring Harbor Symposia on Quantitative Biology, Vol. 60:663-668 (1995) [EXHIBIT 4]
5. McBride, K.E., et al, "Controlled expression of plastid transgenes in plants based on a nuclear DNA-encoded and plastid-targeted T7 RNA polymerase," Proc. Natl. Acad. Sci. USA, Vol. 91:7301-7305 (1994) [EXHIBIT 5]
6. Afione, S.A., et al, "Gene therapy vectors as drug delivery system," Clin. Pharmacokinet, Vol. 28(3):181-189 (1995) [EXHIBIT 6]
7. Wagner, E., et al, "Coupling of adenovirus to transferring-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes," Proc. Natl. Acad. Sci. USA, Vol. 89:6099-6103 (1992) [EXHIBIT 7]
8. Fuerst, T.R., et al, "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," Proc. Natl. Acad. Sci. USA, Vol. 83:8122-8126 (1986) [EXHIBIT 8]
9. Chatterjee, S., et al, "Dual-target inhibition of HIV-1 in vitro by means of an adeno-associated virus antisense vector," Science, Vol. 258:1485-1488 (1992) [EXHIBIT 9]
10. Mason, J., et al, International Patent Application WO 95/19428; "Retroviral vector particles for transducing non-proliferating cells," published July 20, 1995 [EXHIBIT 10]

11. Comb, D.G., et al., European Patent Application O 547 920 A2, "Recombinant thermostable DNA polymerase from archaebacteria," published June 23, 1993 [EXHIBIT 11]
12. Livi, G.P., et al, International Patent Application WO 94/20079; "Human brain phosphodiesterase," published September 15, 1994 [EXHIBIT 12]
13. Overell, R.W., et al, International Patent Application WO 95/28494, "Gene delivery fusion proteins," published October 26, 1995 [EXHIBIT 13]
14. Bushman, Frederic D., International Patent Application WO 95/32225, "Method for site-specific integration of nucleic acids and related products," published November 30, 1995 [EXHIBIT 14]
15. Jolly, D.J., et al, International Patent Application WO 95/31566; "Compositions and methods for targeting gene delivery vehicles," published November 23, 1995 [EXHIBIT 15]
16. Teem, J.L., et al, "Expression of a beta-galactosidase gene containing the ribosomal protein 51 intron is sensitive to the rna2 mutation of yeast," Proc. Natl. Acad. Sci., Vol. 80(14): 4403-4407 (1983) [EXHIBIT 16]

The first fifteen (15) foregoing references (numbers 1-15) were cited in the European Search Report dated September 20, 1999. Reference 16 recently came to the attention of the application's assignee.

A completed Form PTO-1449 listing the 16 above-submitted documents is also attached hereto as Exhibit 17.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith,

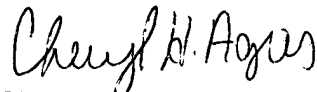
which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Cheryl H. Agris
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Attorney for Applicants

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Form PTO-1449 U.S. Department of Commerce

Atty. Docket No.
ENZ-53(D4)

Serial No. 08/978,635

(REV. 8-83) Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(use several sheets if necessary)

Applicants: Rabbani et al

Filed: November 15, 1997

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
W O	9 5 1 9 4 2 8	7/20/95				
EP O	0 5 4 7 9 2 0	6/23/93				
W O	9 4 2 0 0 7 9	9/15/94				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.).

	Chang, H-K, et al, "Block of HIV-1 infection by a combination of antisense tat RNA and TAR decoys: a strategy for control of HIV-1," <u>Gene Therapy</u> , Vol 1(3):208-216 (1994)
	Cohli, H., et al, "Inhibition of HIV-1 multiplication in a human CD4 lymphocytic cell line expressing antisense and sense RNA molecules containing HIV-1 packaging signal and rev response element(s)," <u>Antisense Research and Development</u> , Vol. 4:19-26 (1994)
	Tani, T., et al, "Activity of chimeric RNAs of U6 snRNA and (-)sTRSV in the cleavage of a substrate RNA," <u>Nucleic Acids Research</u> , Vol. 20(12):2991-2996 (1992)
	Michael, W.M., et al, "Signal sequences that target nuclear import and nuclear export of pre-mRNA-binding proteins," <u>Cold Spring Harbor Symposia on Quantitative Biology</u> , Vol. 60:663-668 (1995)
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EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

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ENZ-53(D4)

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FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRAN- SLATION YES NO
W O 9 5 2 8 4 9 4	10/26/95				
W O 9 5 3 2 2 2 5	11/30/95				
W O 9 5 3 1 5 6 6	11/23/95				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Afione, S.A., et al, "Gene therapy vectors as drug delivery system," <u>Clin. Pharmacokinet</u> , Vol. 28(3):181-189 (1995)
	Wagner, E., et al, "Coupling of adenovirus to transferring-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 89:6099-6103 (1992)
	Fuerst, T.R., et al, "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 83:8122-8126 (1986)
	Chatterjee, S., et al, "Dual-target inhibition of HIV-1 in vitro by means of an adeno-associated virus antisense vector," <u>Science</u> , Vol. 258:1485-1488 (1992)
	Teem, J.L., et al, "Expression of a beta-galactosidase gene containing the ribosomal protein 51 intron is sensitive to the rna2 mutation of yeast," <u>Proc. Natl. Acad. Sci.</u> , Vol. 80(14): 4403-4407 (1983)

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